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C3 1 Cont'd

1, SEQ ID NO 2, SEQ ID NO 3, SEQ ID NO 4, or SEQ ID NO 5 beginning with the amino acid residue in any one of the positions 1 to 5 and ending with the amino acid residue in any one of the positions 100 to 104.

REMARKS

This submission is in response to the Official Action dated January 31, 2002. Applicants submit herewith a Petition for an extension of time for three months with the appropriate fee. Applicants also submit herewith a Notice of Appeal. Claims 26, 27, 29, 30 have been amended. Claims 26-50 are pending. Claims 42-50 have been withdrawn from consideration. Reconsideration of the above identified application, in view of the above amendments and the following remarks, is respectfully requested.

The amendments have been made to expedite allowance of the application. Support for the amendments to claims 26, 27, 29, and 30 can be found in the specification at page 5, lines 1-3.

35 U.S.C. §112 Rejections

35 U.S.C. §112, second paragraph

The Examiner has rejected claims 26-41 under 35 U.S.C. §112, second paragraph as being indefinite. Specifically the Examiner contends that claims 26, 27, 29, 30 and 32-41 are indefinite because it is unclear what is encompassed by the term "homologous." Claims 26, 27, 29 and 30 have been amended to define a

"homologous" sequence as one that is at least 80% identical to the respective sequence. This amendment is supported by the specification at page 5, lines 1-3. Claims 27-33 and 35 are dependent on claim 26, claim 34 is dependent on claim 33 and claims 36-41 are dependent on claim 35. For the foregoing reasons, the applicants submit that the rejection of claims 26-41 based on §112, second paragraph has been overcome and thus request that this rejection be withdrawn.

35 U.S.C. §112, first paragraph

The Examiner has rejected claims 26-41 under §112, first paragraph as failing to meet the enablement requirement. The Examiner states that the specification provides insufficient guidance as to what level of homology and what characteristics define homologous. The applicants respectfully disagree.

The specification defines homologous as a sequence that is at least 80% identical to the respective sequence. *See* specification at page 5, paragraph 1. The term homologous as applied to amino acids is well known in the art to refer to the relationship between the amino acids in terms of their sequence similarity as reflected by percent identity. Homologous sequences may be easily identified by using any of the sequence analysis software well known to those of skill in the art.

The Examiner has further indicated that the specification provides no guidance to enable one to determine, without undue experimentation, the effects of different amino acid substitutions and the nature and extent of the changes that can be made.

The applicants respectfully submit that a skilled user would not need to undertake any undue experimentation to identify such amino acids and that the claimed peptides are fully enabled under the first paragraph of 35 U.S.C. §112.

The test for enablement is whether a person who is reasonably skilled in the art could make and use the claimed invention without undue experimentation, using the disclosure in the patent coupled with information that was known when the patent application was filed. *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988). The proper test is not, therefore, whether any experimentation would be necessary, but instead, if experimentation would be necessary, whether it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976). The fact that experimentation may be complex does not necessarily make it undue. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983). See, also, *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The pending claims in this application all specify peptides whose amino acid sequences are recited with particularity in the pending claims. In view of the description of a homologous sequence as found in the specification, it will be clear to one skilled in the art that the claimed peptide should encompass a sequence that is identical or at least 80% homologous to at least a portion of one or more of the sequences of SEQ ID NOs 1-5 and that the biological activity of the peptide should be maintained. It is within the skill of one in the art to identify those modifications that

will likely result in altered biological activity, without undue experimentation. For example, one would reasonably expect that the substitution of a glycine residue for an alanine residue (or vice versa) would not significantly affect the biological activity of a protein. Therefore, like substitutions or modifications are within the scope of the present invention. As the claimed peptide consists of sequences of known and well-characterized proteins, and the skilled artisan will readily appreciate what modifications would be tolerated.

The applicants submit that claims 26-41 are clearly enabled and request that the rejection of these claims under 35 U.S.C. §112, first paragraph be withdrawn.

35 U.S.C. §102 Rejections

Claims 26, 27, 29, 30 and 33-41 have been rejected under §102(b) as being anticipated by Kilian et al. Specifically, the Examiner has noted that Kilian recites IGA 1 proteases and fragments of such proteases which are 59.1% homologous to SEQ ID NO. 1, 58.6% homologous to SEQ ID NO. 2, 56.9% homologous to SEQ ID NO. 3, 49.5% homologous to SEQ ID NO. 4, and 52.8% homologous to SEQ ID NO. 5.

Anticipation requires that each and every element of the rejected claim(s) be disclosed in a single prior art reference. See, M.P.E.P. § 2131. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Claims 26, 27, 29 and 30 have been amended to more clearly define the peptide as one that is identical or at least 80% homologous to the respective sequence of SEQ ID NOs 1-5. Claim 33 is dependent on claim 26, claim 34 is dependent on claim 33 and claims 36-41 are dependent on claim 35.

Thus, Kilian cannot anticipate the pending claims of this application. Applicants therefore respectfully request that the prior art rejection of claims 26, 27, 29, 30 and 33-41 be withdrawn.

CONCLUSION

Therefore, in view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted,

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Date 7/30/02 Label No. EV028720245-US

I hereby certify that, on the date indicated above, this paper or fee was deposited with the U.S. Postal Service & that it was addressed for delivery to the Assistant Commissioner for Patents, Washington, DC 20231 by "Express Mail Post Office to Addressee" service.

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D Beck

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PATENT TRADEMARK OFFICE

Docket No: 7101/0E616

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Mark ACHTMAN; Monique MOREAU

Serial No.: 09/142,970 Art Unit: 1645

Confirmation No.: 2916

Filed: 04/02/99 Examiner: J. Graser

For: IGA1 PROTEASE FRAGMENT AS CARRIER PEPTIDE

MARK-UP OF CLAIMS FOR AMENDMENT
PURSUANT TO 37 C.F.R. §1.121

Box AF
Hon. Commissioner of Patents and Trademarks
Washington, DC 20231

July 30, 2002

Sir:

26. (Twice Amended) An isolated peptide consisting of 40 to 200 amino acid residues, wherein the peptide comprises an amino acid sequence having 40 or more amino acids that are identical or at least 80% homologous to an amino acid sequence

selected from the group consisting of amino acid sequences:

a. of SEQ ID NO 1, beginning with the amino acid residue in any one of positions 1 to 5 and ending with the amino acid residue in any one of positions 40 to 104;

b. of SEQ ID NO 2, beginning with the amino acid residue in any one of positions 1 to 5 and ending with the amino acid residue in any one of positions 40 to 104;

c. of SEQ ID NO 3, beginning with the amino acid residue in any one of positions 1 to 5 and ending with the amino acid residue in any one of positions 40 to 104;

d. of SEQ ID NO 4, beginning with the amino acid residue in any one of positions 1 to 5 and ending with the amino acid residue in any one of positions 40 to 104; and

e. of SEQ ID NO 5, beginning with the amino acid residue in any one of positions 1 to 5 and ending with the amino acid residue in any one of positions 40 to 104.

27. (Amended) The peptide of claim 26, wherein the peptide comprises at least 40 amino acids of the amino acid sequence shown in SEQ ID NO 1, beginning with the amino acid residue in any one of the positions 1 to 5 and ending with an amino acid residue in any one of positions 40 to 104, or an 80% homologous

sequence.

29. (Amended) The peptide of claim 26, wherein the peptide comprises a sequence of at least 70 amino acid residues having an amino acid sequence that is identical or at least 80% homologous to an amino acid sequence of SEQ ID NO 1, SEQ ID NO 2, SEQ ID NO 3, SEQ ID NO 4, or SEQ ID NO 5 beginning with the amino acid residue in any one of positions 1 to 5 and ending with the amino acid residue in any one of the positions 70 to 104.

30. (Amended) The peptide of claim 26, wherein the peptide comprises a sequence of at least 100 amino acid residues having an amino acid sequence that is identical or at least 80% homologous to an amino acid sequence of SEQ ID NO 1, SEQ ID NO 2, SEQ ID NO 3, SEQ ID NO 4, or SEQ ID NO 5 beginning with the amino acid residue in any one of the positions 1 to 5 and ending with the amino acid residue in any one of the positions 100 to 104.

Respectfully submitted,

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